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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,128	04/09/2004	Jun E. Lee	0942.5690001/RWE/JKM	8246

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,128	LEE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to composition for use in synthesizing one or more nucleic acids; and claims 55-71, drawn to kit for use in labeling one or more nucleic acid molecules, class 435, subclass 6.

II. Claims 32-43, drawn to nucleic acid molecule, classified in class 536, subclass 23.1.

III. Claims 44-54, drawn to method of synthesizing one or more nucleic acid molecules, classified in class 435, subclass 91.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different products- a composition and a compound, that are each comprised of different elements and which have different properties.

3. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process such as by solid phase synthesis.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used as standards in a mass spec analysis.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Patentably Distinct Species

6. In the event of either Group I, II, or III is elected, applicant must also elect a single species from each of the identified grouping(s) for consideration

7. This application contains claims directed to the following patentably distinct species:

a. In the event that applicant elects the invention of Group I, the following election is applied;

i. Composition / kit comprises nucleic acid template

(1) Yes

(a) DNA

(b) RNA

(i) mRNA

(ii) Population of mRNA molecules

(2) No

ii. Detectable label present

(1) Yes

(a) Fluorescent label

(i) Cyanine dye

1) Cy3

2) Cy5

(ii) Alexa dye

(2) No

iv. One or more enzymes with transcriptase activity

(1) Yes

(2) No

v. Modified nucleotides present in composition / kit

(1) Yes

(a) One or more modified nucleotides present

(i) Reactive primary amine

(ii) Aminoallyl-dUTP

(iii) Aminohexyl-dATP

(b) Two or more modified nucleotides present

(i) Aminoallyl-dUTP

(ii) Aminohexyl-dATP

(2) No

b. In the event that applicant elects the invention of Group II, the following election is applied:

i. Modified nucleotides present

(1) Yes

(a) One or more modified nucleotides present

(i) Reactive primary amine

(ii) Aminoallyl-dUTP

(iii) Aminohexyl-dATP

(b) Two or more modified nucleotides present

(iv) Aminohexyl-dATP and aminoallyl-dUTP

(v) Reactive primary amine

ii. Detectable label present

(1) Yes

(a) Fluorescent label

(b) Cyanine dye

(i) Cy3

(ii) Cy5

(2) No

c. In the event that the invention of Group III is elected, the following election of patentably distinct species applies:

i. At least one modified nucleotide is

(1) Aminoally-dUTP

(2) Aminohexyl-dATP

ii. Nucleic acid template

(1) mRNA

(2) Population of mRNA molecules

iii. Detectable label present

(1) Yes

(a) Fluorescent label

(b) Cyanine dye

(i) Cy3

(ii) Cy5

(c) Alexa dye

(2) No

8. CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

9. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. The species are independent or distinct because they are comprised of different compounds that have different compositions and properties.

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be

allowable. Currently, claims 1 and 55 are generic for Gr0oup I; claim 32 is generic for Group II; and claim 55 is generic fro Group III.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 verse.

15. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS